

WHAT IS CLAIMED IS:

1. A pharmaceutical formulation comprising:
 - a) a pharmaceutically active amount of erythropoietin;
 - b) a pharmaceutically acceptable pH buffering agent to provide a pH in a range of about pH 6 to about pH 9;
 - c) a tonicity agent in a concentration range of about 0 to about 200 millimolar; and
 - d) sodium carboxymethyl ether cellulose in a concentration range of about 0.5% to about 7% total formula weight, said CMC having a molecular weight in a range of about 50,000 daltons to about 1,000,000 daltons.
2. The formulation of claim 1 wherein the erythropoietin is selected from a group consisting of recombinant human erythropoietin, epoietin alfa, epoietin omega, darbepoetin alfa, and PEG conjugated erythropoietin.
3. The formulation of claim 1 wherein the pH buffering agent concentration is in the range of about 10 mM to about 30 mM and wherein the pH buffering agent is a sodium phosphate monobasic / sodium phosphate dibasic buffer system.
4. The formulation of claim 1 wherein the tonicity agent is selected from a group consisting of NaCl, KCl, and glycine.
5. The formulation of claim 1 wherein the tonicity agent is NaCl and the NaCl concentration is about 75 mM to about 125 mM.

6. The formulation of claim 1 wherein the pH of the formulation is in the range of about 6.5 to about 7.4.
7. A method of treating a subject in need of such treatment comprising administering to the subject a pharmaceutical formulation according to claim 1.
8. The method of claim 7 wherein the pharmaceutical formulation is administered in accordance with a regimen of administering thrice per two weeks, once per week, once per two weeks, once per three weeks, once per month, once per five weeks, or once per six weeks.
9. The method of claim 8 wherein the effective daily dosing of erythropoietin is from about 4000 to about 9000 I.U.
10. The method of claim 9 wherein the effective daily dosing of erythropoietin is greater than 10,000 I.U.
11. A method of formulation comprising the steps, in any order:
 - a) providing a pH buffered erythropoietin sample;
 - b) admixing a quantity of CMC to the pH buffered erythropoietin sample sufficient to provide a final concentration of about 0.5% to about 7% CMC total formula weight;
 - c) admixing a quantity of NaCl to the pH buffered erythropoietin sample sufficient to provide a final concentration of about 0 mM to about 170 mM NaCl; and
 - d) adjusting the pH buffered erythropoietin sample with water sufficient to provide a predetermined final formulation volume and erythropoietin potency.

12. A pharmaceutical formulation comprising:
- a) a pharmaceutically active amount of a protein;
 - b) a pharmaceutically acceptable pH buffering agent to provide a pH in the range of about pH 4.5 to about pH 9;
 - c) a tonicity agent in the concentration range of about 0 to about 200 millimolar; and
 - d) Sodium carboxymethyl ether cellulose in the concentration range of about 0.5% to about 7% total formula weight, said CMC having a molecular weight in the range of about 50,000 daltons to about 1,000,000 daltons.
13. The formulation of claim 12 wherein the protein is selected from a group consisting of insulin, motilin, gastrin, prolactin, adrenocorticotrophic hormone (ACTH), growth hormone (GH), keratinocyte growth factor (KGF), stem cell factor (SCF), thrombopoietin, osteoprotegerin (OPG), obesity protein (OB protein), leptin, granulocyte colony-stimulating factor (G-CSF), alpha interferon, beta interferon, gamma interferon, interleukin 2, fibroblast growth factors (FGF), insulin-like growth factors (IGF), macrophage colony stimulating factor (M-CSF), granulocyte macrophage colony stimulating factor (GM-CSF), colony stimulating growth factors (CSFs), tumor necrosis factor (TNF), thyroid stimulating hormone (TSH), luteinizing hormone (LH), follicle stimulating hormone (FSH), human chorionic gonadotropin (HCG), neurotrophic growth factor (NGF), neurotrophic factor 3 (NT3), neurotrophic factor 4 (NT4), brain-derived neurotrophic factor (BDNF), glial cell line derived neurotrophic factor (GDNF), platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF), bone morphogenetic protein (BMP), megakaryocyte growth differentiation factor (MGDF), Factor VII, Factor VIIa, Factor VIII, Factor IX, superoxide dismutase (SOD), tissue plasminogen activator (TPA), urokinase, streptokinase, kallikrein, alpha-galactosidase, pancreatic

ORT-1531

RNAase, platelet activating factor acetylhydrolase, interleukin-1 receptor antagonist (IL-1ra), Infliximab, antibodies, and etanercept.

- 5 14. The formulation of claim 12 wherein the pH buffering agent concentration is in the range of about 10 mM to about 30 mM and wherein the pH buffering agent is a sodium phosphate monobasic / sodium phosphate dibasic buffer system.
- 10 15. The formulation of claim 12 wherein the tonicity agent is selected from a group consisting of NaCl, KCl, and glycine.
- 15 16. The formulation of claim 12 wherein the tonicity agent is NaCl and the NaCl concentration is about 75 mM to about 125 mM.
17. The formulation of claim 12 wherein the pH of the formulation is in the range of about 6.5 to about 7.4.
18. A method of treating a subject comprising administering to the subject a pharmaceutical formulation according to claim 12.
- 20 19. The method of claim 18 wherein the pharmaceutical formulation is administered in accordance with a regimen of administering thrice per two weeks, once per week, once per two weeks, once per three weeks, once per month, once per five weeks, or once per six weeks.
- 25